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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,579	11/02/2000	Brian M. Fendly	P1053R1D1	5667

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EXAMINER	
HUNT, JENNIFER ELIZABETH	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/705,579	FENDLY, BRIAN M.	
	Examiner	Art Unit	
	Jennifer E Hunt	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 42-68 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 42-68 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 42-56, drawn to a method of treating a tumor or cancer by administering an anti-ErbB2 antibody, classified in class 424, subclass 130.1 and 155.1.

II. Claims 57-66 in part, drawn to a method of treating a tumor or cancer by administering an anti-ErbB2 antibody and further comprising combining a second therapeutic regimen wherein the second therapeutic regimen is a chemotherapeutic agent or growth inhibitory agent, classified in class 424, subclass 130.1, and 155.1, and class 514, subclass 2.

III. Claims 57-66 in part, drawn to a method of treating a tumor or cancer by administering an anti-ErbB2 antibody and further comprising combining a second therapeutic regimen wherein the second therapeutic regimen is an anti-estrogen compound, classified in class 424, subclass 130.1, and 155.1.

IV. Claims 57-66 in part, drawn to a method of treating a tumor or cancer by administering an anti-ErbB2 antibody and further comprising combining a second therapeutic regimen wherein the second therapeutic regimen is an anti-progesterone compound, classified in class 424, subclass 130.1, and 155.1.

V. Claim 57-66 in part, drawn to a method of treating a tumor or cancer by administering an anti-ErbB2 antibody and further comprising combining a second therapeutic regimen wherein the second therapeutic regimen is another antibody, classified in class 424, subclass 130.1, and 155.1.

VI. Claims 57-66 in part, drawn to a method of treating a tumor or cancer by administering an anti-ErbB2 antibody and further comprising combining a second therapeutic regimen wherein the second therapeutic regimen is a cytokine, classified in class 424, subclass 130.1, and 155.1.

VII. Claims 57-66 in part, drawn to a method of treating a tumor or cancer by administering an anti-ErbB2 antibody and further comprising combining a second therapeutic regimen wherein the second therapeutic regimen is radiation therapy, classified in class 424, subclass 130.1, and 155.1.

VIII. Claims 67-68, drawn to an article of manufacture, classified in class 424, subclass 130.1, and 155.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group VIII and Groups I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the

product of Group VIII can be used for a materially different process, such as to detect or isolate ErbB2 positive cancer.

The methods of Groups I-VII are completely different methods which require different starting materials, involve different method steps, and further which result in distinct therapeutic outcomes. The method of Group I requires administration of an anti-ErbB2 antibody alone. The method of Group II requires administration of an anti-ErbB2 antibody and a chemotherapeutic or growth inhibitory agent. The method of Group III requires administration of an anti-ErbB2 antibody and an anti-estrogen compound. The method of Group IV requires administration of an anti-ErbB2 antibody and an anti-progesterone compound. The method of Group V requires administration of an anti-ErbB2 antibody and an additional antibody. The method of Group VI requires administration of an anti-ErbB2 antibody and a cytokine. The method of Group VII requires administration of an anti-ErbB2 antibody and radiation therapy. Single agent therapy is different from multiple agent therapy, because a single agent has a different dose and therapeutic efficacy than multiple agents. Further variation of a second agent in multiple agent therapy results in different dosages and therapeutic efficacies, because completely different secondary therapeutic regimens produce variant therapeutic effects, particularly when combined with another agent.

Thus because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, and because these inventions are distinct for the reasons given above and have acquired a separate

status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Species Election:

This application contains claims directed to the following patentably distinct species of the claimed invention:

A- If any of Groups I-VIII are elected, applicant must further elect a species of cancer, for example from those listed at page 19, line 27-page 20, line 5 of the specification.

These are completely different disease processes, having different symptoms and requiring different therapeutic regimens.

B- If Group II is elected, applicant must further elect a type of chemotherapeutic or growth inhibitory agent, for example, from those listed at page 20, lines 7-27 of the specification.

These chemotherapeutic and growth inhibitory agents are completely different products, having different structures, and different pharmaceutical effects.

C- If Group III is elected, applicant must further elect a type of anti-estrogen compound, for example, from those listed at page 50, lines 2-4 of the specification.

These anti-estrogen compounds are completely different products, having different structures, and different pharmaceutical effects.

D- If Group IV is elected, applicant must further elect a type of anti-progesterone compound, for example, from those listed at page 50, lines 2-4 of the specification.

These anti-progesterone compounds are completely different products, having different structures, and different pharmaceutical effects.

E -If Group V is elected, applicant must further elect a type of antibody which is administered:

E1 - an antibody which binds a cancer antigen other than ErbB2

E2- an antibody which binds ErbB2

Further, if E1 is elected, applicant must further elect a type of non-ErbB2 antibody, for example, from those listed at page 50, lines 4-6 of the specification.

Further, if E2 is elected, applicant must further elect a type of ErbB2 antibody.

These antibodies are completely different products, which bind to distinct molecules, and further which have different structures, and different pharmaceutical effects.

F- If Group VI is elected, applicant must further elect a type of cytokine, for example, from those listed at page 20, line 28-page 21, line 13 of the specification.

These cytokines are completely different products, having different structures, and different pharmaceutical effects.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E Hunt whose telephone number is (703) 308-7548. The examiner can normally be reached on Monday-Friday, 6-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Jennifer E Hunt
Examiner
Art Unit 1642

jeh
January 29, 2002

Sheela J. Huff
SHEELA HUFF
PRIMARY EXAMINER